K061496

JUN 28 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SAS™ Legionella Test

The 510(k) summary of safety and effectiveness submission is in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitted by:	SA Scientific, Ltd. 4919 Golden Quail San Antonio, TX 78240
Establishment Reg. No.	1645225
Contact Person:	Veronica DeLeon
Date Prepared:	May 30, 2006
Proprietary Name:	SAS™ Legionella Test
Common Name:	SAS™ Legionella Test, SAS™ *Legionella pneumophila* Test
Classification Name:	Legionella, SPP., Elisa
Device Classification:	21 CFR 866.3300
Regulatory Class:	Class II
Product Code:	MJH
Substantial Equivalence:	Binax™ Now® Legionella Urinary Antigen Test manufactured by Binax™ Inc., Portland, Maine
Device Description:	The SAS™ Legionella test utilizes a combination of polyclonal antibodies against the antigens of *Legionella pneumophila*. The SAS™ Legionella test begins with the addition of urine to the test device. The specimen is absorbed by the sample pad and then moves through the conjugate pad which contains dried gold conjugated antibodies which are specific for *Legionella pneumophila* antigens; if the Legionella antigens are present in the urine sample, a "half-sandwich" immunocomplex is formed. This immuno-complex then migrates via capillary action along a nitrocellulose membrane containing immobilized antibodies to *Legionella pneumophila* antigens. The immobilized antibodies bind the "half-sandwich" immuno-complex to

form a "whole sandwich" immuno-complex. Thus, when the "whole sandwich" is formed, a visible, pink colored line develops in the specimen zone on the test device. In the absence of a Legionella antigen, a "sandwich" immuno-complex is not formed and a negative result is indicated. To serve as a procedural control, a pink colored control line will always appear in the control zone regardless of the presence or absence of Legionella antigen. The test is available in cassette format.

Intended Use:

The SAS™ Legionella Test is a visually read, in vitro immunochromatographic rapid assay for the presumptive qualitative detection of *Legionella pneumophila* serogroup 1 antigens in human urine. This test is intended to aid in the presumptive diagnosis of Legionnaires' disease in conjunction with culture and other methods for patients with signs and symptoms of pneumonia. This test is for prescription use only.

Quality Controls:

The SAS™ Legionella Test provides two (2) internal procedural controls. It is recommended that external quality controls should be performed on each new test kit box opened. Positive and negative external controls are supplied separately.

Device Comparison:

The SAS™ Legionella Test and Binax™ Now® Legionella Urinary Antigen Test are rapid immunoassays tests utilizing immunochromatographic technology for the visualization of *Legionella pneumophila* antigen. Each utilizes an antibody conjugated to colored particles and an antibody printed onto a membrane.

Performance Summary:

The SAS™ Legionella Test performed substantially equivalent to the predicate device, Binax™ Now® Legionella Urinary Antigen Test and to culture. This was verified by comparison of frozen and fresh urine specimens.

Cross reactivity and interference studies were performed on viral and bacterial strains commonly found in human urine. None of the organisms interfered or cross-reacted with the performance of the SAS™ Legionella Test.

Prepared by: Veronica DeLeon Date: 6/21/07

Veronica DeLeon
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 8 2007

Veronica DeLeon
Regulatory Affairs
SA Scientific, Ltd.
4919 Golden Quail
San Antonio, TX 78240

Re: k061496
Trade/Device Name: SAS™ Legionella Test
Regulation Number: 21CFR 866. 3300
Regulation Name: Haemophilus spp. Serological Reagents
Regulatory Class: Class II
Product Code: MJH
Dated: May 30, 2006
Received: May 31, 2006

Dear Ms. DeLeon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

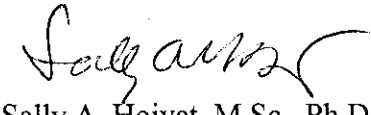
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

INDICATIONS FOR USE

Applicant: SA Scientific, Inc.
4919 Golden Quail
San Antonio, TX. 78240
Ph: (210) 699-8800 Fax: (210) 699-6545

Establishment Reg. No.: 1645225

501(k) Number: K061496

Device Names: SAS™ Legionella Test

Indications for Use:

The SAS™ Legionella Test is a visually read, in vitro immunochromatographic rapid assay for the presumptive qualitative detection of *Legionella pneumophila* serogroup 1 antigens in human urine. This test is intended to aid in the presumptive diagnosis of Legionnaires' disease in conjunction with culture and other methods for patients with signs and symptoms of pneumonia. This test is for prescription use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

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